MAR 2 6 2002

K010131

510(k) SUMMARY

DATE: January 11, 2001

APPLICANT INFORMATION:

Submitter's Name:	Aksys, Ltd
Address:	2 Marriott Drive Lincolnshire, IL 60069
Contact Person:	Jan L. Zorn
Phone Number:	(847) 229-2109
Fax Number:	(847) 229-2300

DEVICE INFORMATION:

Trade Name:	PHD® Personal Hemodialysis System
Common Name:	Hemodialysis equipment
Classification Name:	High permeability hemodialysis system (per 21 CFR 876.5860) Water purification system for hemodialysis (per 21 CRF 876.5665)

SUBSTANTIALLY EQUIVALENT DEVICES:

Hemodialysis Delivery Systems

1. Gambro Multipurpose System MPS-10
   Gambro, Inc. (K881270)
2. Fresenius 2008 Touch Panel Control Dialysis System
   Fresenius USA, Inc. (K890824)
3. RSP® Hemodialysis Machine
   Travenol Laboratories, Inc. (Pre-Amendment)

Reuse Equipment for Hemodialysis

4. HR 3000 Home Patient Reprocessing Device
   Colorado Medical, Inc. (K841153)
5. Renatron II Dialyzer Reprocessing System
   Minntech Corp. (K904210)

Water Purification Systems for Hemodialysis

6. Gambro WRO 10-01 Water Purification Monitor
   Gambro, Inc. (K811678)
7. ZyzaTech Series Reverse Osmosis Systems
   ZyzaTech Water Systems, Inc. (K964539)

Arterial-Venous Blood Tubing Sets for Hemodialysis

8. Gambro Venous Blood Line
   Gambro, Inc. (K770691)
9. Erika Model 9608 Arterial Blood Line
   National Medical Care, Inc. (K870722)

Dialysate Chemical Concentrates

10. Hemodialysis Bath Concentrate Solutions for Hemodialysis.
    Dial Medical of Florida, Inc. (K864265)

11. Liquiflo™ and Biocarb™ Dry Bicarbonate Concentrates
    Fresenius USA, Inc. (K896111)

Transducer Protectors

12. Dualex® Transducer Protector
    Millipore Corporation (K934069)

DEVICE DESCRIPTION:

The PHD® Personal Hemodialysis System is an automated high flux hemodialysis system using a double needle configuration. It is designed to perform safe and effective personal hemodialysis as prescribed by the patient's physician, while minimizing the time and effort to perform each treatment. A computer-like touch screen prompts the operator through each step of the procedure.

The PHD System consists of several components that combine to deliver hemodialysis and perform ultrafiltration. These include the PHD Instrument (PHDi), the PHD Water Pre-Treatment System (WPS), the PHD Blood Tubing Set (BTS), the PHD Chemical Concentrate Bottles (CCBs), and the PHD Transducer Protector (TP).

The PHD Instrument orchestrates and performs the entire pre-treatment, treatment, and post treatment cycle. It accomplishes this by working in conjunction with the WPS (or equivalent), BTS, CCBs, TP, and a commercially

available hollow fiber membrane dialyzer. Between treatments, the system automatically cleans and disinfects the blood tubing set, dialyzer, and all other components in the fluid pathway. Also, the machine checks the efficiency and integrity of the dialyzer. The PHD Instrument electronically stores information about the patient, prescription, treatment schedule, and machine set-up while allowing for updates according to individual needs.

INTENDED USE:

- Indicated for treatment of the chronic or acute uremic patient where hemodialysis, including high flux dialysis, is prescribed by the physician.
- Indicated for hemodialysis in a variety of environments, to include acute care facility, chronic dialysis facility, self care facility, or home setting, where the patient has been trained and certified to be competent in the use of this device by the attending physician.

COMPARISON TO PREDICATE DEVICES:

The Premarket Notification demonstrates substantial equivalence to the identified predicate devices by comparison of design, components, technology, functionality, and intended use.

Hemodialysis Delivery Systems – Common Technological Characteristics

- Utilizes single-pass and recirculation of the hemodialysis solution from a reservoir.
- Mixes concentrate with water in the appropriate proportions to produce dialysate.
- Delivers dialysate at the appropriate temperature and ionic concentration to the dialyzer.
- Removes the appropriate amount of liquid from the patient's blood.
- Along with the dialyzer and blood pump, acts as an artificial kidney.
- Warms incoming water and dialysate with a heater.
- Monitors the temperature and conductivity of the dialysate before it enters the dialyzer.
- Controls the flow of dialysate to and from the dialyzer.
- Regulates the pressure in the ultrafiltration circuit so that a precise amount of dialysate is removed from the post dialyzer circuit which causes a like amount of liquid to be removed from the dialyzed blood compartment.
- Controls the blood flow through the extracorporeal circuit by use of a blood pump.
- Automatically cleans, disinfects, and rinses fluid pathways.
- Monitors system functions and alerts (alarms) operator when abnormal functions or conditions are detected.

- Incorporates an integrated reverse osmosis based water purification system.
- Produces an on-line sterile electrolyte-containing solution which can be infused into the extracorporeal circuit for priming, rinse-back, and infusion of replacement solution during patient treatment.

Reuse Equipment for Hemodialysis – Common Technological Characteristics

- Provides *in situ* cleaning and disinfection of a previously used hemodialyzer and blood tubing set (arterial and venous lines) for single patient reuse
- Measures the performance of the dialyzer during the reprocessing / reuse of the hemodialyzer by means of a sodium clearance
- Measures dialyzer integrity by means of a pressure decay test.

Water Purification Systems for Hemodialysis – Common Technological Characteristics

- Provides water purification for a single patient hemodialysis machine utilizing reverse osmosis of pre-treated water through a spiral wound polyamide thin film reverse osmosis membrane
- Utilizes particle filters, and carbon filters for the pre-treatment of water
- Integrates alarm systems for monitoring poor water quality
- Provides water temperature and pressure regulation for incoming water
- Utilizes conductivity to monitor water quality

Arterial-Venous Blood Tubing Sets for Hemodialysis – Common Technological Characteristics

- Incorporates standard diameter and wall thickness tubing for the extracorporeal circuit
- Incorporates conventional connectors and component parts
- Incorporates a blood pump tubing segment, which can be used with a peristaltic blood pump.
- Designed for reprocessing and reuse in the same patient
- Incorporates arterial pressure monitoring capability in the extracorporeal circuit
- Incorporates a venous drip chamber without a filter.
- Incorporates venous pressure monitoring capability in the extracorporeal circuit

Dialysate Chemical Concentrates –Common Technological Characteristics

- Contains the essential electrolytes and dextrose in the appropriate concentrations that when proportioned with the appropriate volume of pre-treated water, will provide safe and effective hemodialysis solutions according to the physician's prescription.
- Concentrate solutions and powders are packaged and stored in containers made of high density polyethylene
- Requires both bicarbonate concentrate and acidified concentrate that when combined with pre-treated water, produce the hemodialysis solution.

Transducer Protectors – Common Technological Characteristics

- Provides a sterile hydrophobic barrier between the extracorporeal circuit and the venous pressure monitoring device contained/integrated into the hemodialysis machine.
- Utilizes a membrane barrier made of PTFE.
- Freely transmits gas, but does not allow the passage of fluids.
- Removes, by filtration, particles and microorganisms larger the 0.2 μm.

CLINICAL TESTING:

Twenty three patients from 3 sites contributed substantial equivalence data to the PHD clinical study. Parameters used to establish the substantial equivalence of the PHD System were accuracy of delivered Kt/V, accuracy of ultrafiltration, and incidence of adverse events.

Clinical data has shown the PHD System is substantially equivalent to conventional equipment in terms of efficacy, accuracy, and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 2002

Ms. Jan L. Zorn
Director of Regulatory Affairs
Aksys, Ltd.
Two Marriott Drive
LINCOLNSHIRE IL 60069

Re: K010131
Trade/Device Name: Aksys PHD® Personal Hemodialysis System
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: December 21, 2001
Received: December 26, 2001

Dear Ms. Zorn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

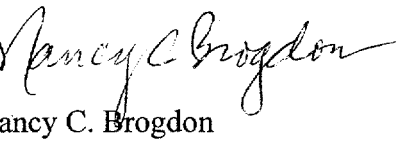
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K010131

Device Name: **PHD® Personal Hemodialysis System**

Indications for Use:

- Indicated for the treatment of the chronic or acute uremic patient where hemodialysis, including high flux dialysis, is prescribed by the physician.
- Indicated for hemodialysis in a variety of environments, to include acute care facility, chronic dialysis facility, self care facility, or home setting, where the operator has been trained and certified to be competent in the use of this device by the attending physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K010131

Prescription Use ✓ OR Over-the Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)